# EXHIBIT 21

# TRANSVAGINAL MESH REMOVAL

## Transvaginal mesh removal at a glance

- Women who are suffering from pelvic organ prolapse (http://urogyn.coloradowomenshealth.com/patients/library/pelvic-organ-prolapse/) (POP) may opt for surgery to treat serious symptoms that do not improve with lifestyle changes or other devices to help support the prolapsed organs.
- Several surgical methods of repairing pelvic floor disorders exist, including a method known as transvaginal mesh implantation.
- Frequently reported complications from transvaginal mesh include chronic pain, infection, bleeding, pain during intercourse, urinary problems, and exposure of the mesh through the vagina.
- Transvaginal mesh removal is a technically complex surgical procedure in which surgeons attempt to remove as much of the mesh as possible.
- Complete mesh removal is possible for some women, while only part of the mesh can be removed in other women due to complicated issues from the type of mesh that was originally used.

## The history of using mesh for pelvic organ prolapse

Pelvic organ prolapse (POP) is one of the most common reasons for women to have surgery, with approximately 200,000 inpatient surgical procedures performed for POP in the U.S. each year.

A woman's risk of requiring surgery for prolapse is approximately 7 percent by age 80. Of those who have surgery, an estimated 13 percent will require a repeat operation within five years and as many as 29 percent will undergo another surgery for prolapse or a related condition at some point during their life.

In the past several years, there was an increase in the use of synthetic and biologic mesh for transvaginal prolapse surgery. This was largely driven by the availability and marketing of commercially available pre-packed mesh delivery systems or “mesh kits.”

Unfortunately, an increasing number of women report serious complications from transvaginal mesh that severely impact their quality of life.

In 2011, the U.S. Food and Drug Administration (FDA) issued a safety communication stating that the use of transvaginal mesh may put women at a higher risk of complications without increased benefit to their quality of life. This is what has sparked a large number of television commercials about the issue.

The most frequent complications noted in the FDA statement included infection, pain, urinary problems, vaginal scarring and recurrence of prolapse and/or incontinence. Another complication cited by the FDA was erosion, in which the mesh gradually dislodges from the vaginal wall where it was implanted and moves into the surrounding tissue and organs. Erosion is also called extrusion or exposure when the mesh protrudes from the opening of the vagina.

The FDA also noted some cases of vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including painful intercourse (dyspareunia).

## Surgical removal of transvaginal mesh

Women who have transvaginal mesh implants may experience symptoms caused by the surgical procedure itself or from problems with the mesh. In transvaginal mesh removal surgery, physicians attempt to remove as much of the mesh as possible and repair the damaged tissue.

Subsequent surgery may be necessary to correct the original prolapse and/or any other serious complications from the mesh.

Because transvaginal mesh is considered a permanent implant, surgery to remove the mesh can be difficult and may increase a woman’s risk of additional complications or symptoms. Over time, the tissue grows into and around the mesh, so removing the mesh without damaging the surrounding tissue and organs is a delicate process that varies depending on each individual woman’s circumstances.

The amount of mesh the surgeon will be able to remove may also depend on the type of mesh or mesh kit that was used in the original surgery.

## Treatment options for transvaginal mesh complications

Mesh erosion, one of the most common post-operative complications, can be treated with close observation, treatment with estrogen cream, office excision (removal of the mesh), excision in the operating room, and removal of the maximum amount of mesh or graft.

For women who are not sexually active and have very small amounts of erosion, observation may be the preferred for of treatment. The patient will be seen by a physician three months and six months after the initial consultation, and then will have follow-up examinations every six to 12 months.

Although the erosion may not heal on its own during that time, it rarely worsens. For most patients, however, we recommend using vaginal estrogen in addition to observation.

If the erosion continues after estrogen use or if the patient is not able to use vaginal estrogen, mesh excision is another treatment. Physicians may be able to perform mesh excision as an outpatient procedure if the mesh exposure is very small (less than 5 mm). In this procedure, the affected area is injected with local anesthetic, and the physician removes the exposed mesh. If the woman prefers, this procedure may be performed in the operating room instead.

When the mesh exposure is larger than 5mm, inpatient surgery is necessary to remove the exposed mesh and repair the affected tissues. After the operation, vaginal estrogen to heal the tissue will be used until the area is well healed.

In cases where mesh excision was unsuccessful, where the amount of exposed mesh is larger than 5mm, or when the woman experiences infection, fistula, or chronic pain, we advocate removing the majority of the mesh in a second surgery.

While this mesh excision procedure requires an expert set of skills, our experience suggests that it can be done safely with few complications and high relief of symptoms, although some symptoms may persist after the procedure.

Complete removal of the mesh may be possible if the mesh was originally placed from a completely transvaginal approach. If trocars were used to place the mesh, as is the case with many commercially available mesh kits, it is often not possible or advisable to remove the arms of the mesh, because they pass through the ischiorectal fossa (a wedge-shaped space in the pelvic area) and/or obturator muscle. In these cases, we advocate removal of as much of the mesh as possible through a vaginal approach while leaving the mesh arms in place.

Contact us to request an appointment (http://urogyn.coloradowomenshealth.com/contact/appointment/) with one of our Urogynecologists to learn more about options for removing transvaginal mesh.


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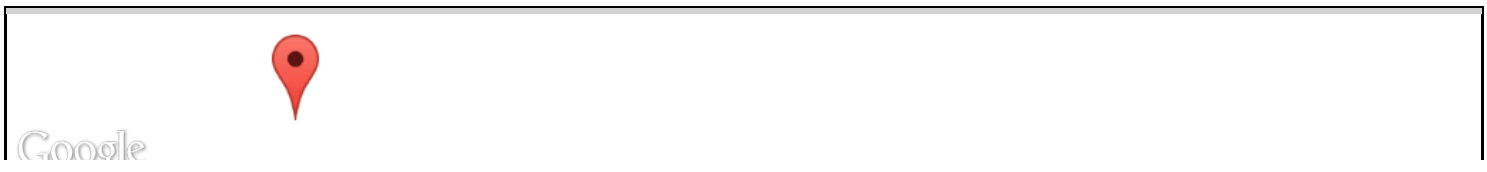

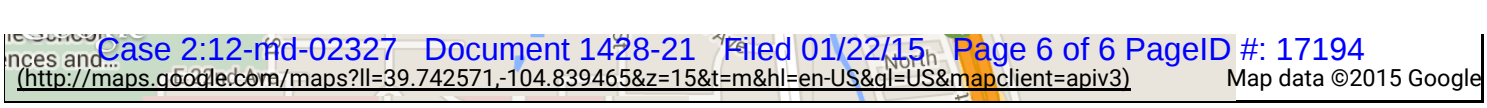


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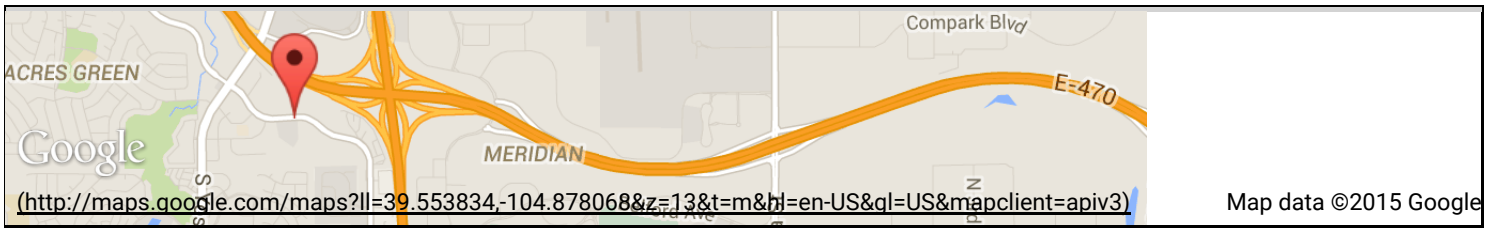


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University of Colorado Urogynecology is the largest female pelvic medicine and reconstructive surgery practice in Colorado. Each doctor is fellowship-trained and double board certified, including certification in Female Pelvic Medicine and Reconstructive Surgery. We are dedicated to saving and restoring each patient's quality of life by providing women of all ages with comprehensive evaluation, treatment and management of female pelvic health problems.

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